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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/290,049 04/12/99 SMITH

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021005 HM22/1214  
HAMILTON BROOK SMITH AND REYNOLDS, P.C.  
TWO MILITIA DR  
LEXINGTON MA 02421-4799

EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

13

DATE MAILED:

12/14/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

File Copy

**Office Action Summary**Application No.  
**09/290,049**

Applicant(s)

**Smith et al**

Examiner

**Li Le**Group Art Unit  
**1645**☒ Responsive to communication(s) filed on Sep 20, 1900☒ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**☒ Claim(s) 1-19 is/are pending in the applicatOf the above, claim(s) 12-14, 18, and 19 is/are withdrawn from consideration☐ Claim(s) \_\_\_\_\_ is/are allowed.☒ Claim(s) 1-11 and 15-17 is/are rejected.☐ Claim(s) \_\_\_\_\_ is/are objected to.☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.**Application Papers**☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119**☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).**Attachment(s)**☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1645

### DETAILED ACTION

1. Applicant's amendment filed on Sep 20, 2000 (Paper Number 12) has been received and entered. Claims 1, 5, and 15 have been amended, consequently claims 1-11 and 15-17 are being examined in the instant application.

2. The rejection of claims 1, 4- 5, 7-11, 15, 17 under 35 U.S.C. 112, second paragraph, as being indefinite as there is no defined specific amino acid sequence in the claims. *is maintained.*

In response to applicant's argument that claims 1, 5, and 15 have been amended to recite that the glucosyltransferase is an S mutans glucosyltransferase, the art teaches that in S mutans, there are at least three different glucosyltransferases which are encoded by three different genes and express different enzyme activity (Chia et al Infection and Immunity , 61 (11): 4689-4695, 1993 in PTO-1449). Therefore, without reciting a specific amino acid sequence, one of ordinary skill in the art cannot isolate the protein vaccine which *specifically has* particular amino acids at the particular positions in the claimed polypeptide from a glucosyltransferase due to the existence of other glucosyltransferase polypeptide in ~~the~~ nature.

3. The objection of claims 15-17 under 37 CFR 1.75 as being a substantial duplicate of claims 1-2, and 4 is withdrawn in view of applicant's remarks.

4. Item listed on form PTO-1449 filed on Sep 20, 2000 has ~~be~~ *been* considered by the examiner.

5. The rejection of claims 1-4 and 15-17 under 35 U.S.C. 102(b) as being anticipated by Shiroza et al (J Bacteriol 169: 4263-4270, 1987) is maintained.

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In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., useful peptides will be less than the complete amino acid sequence of the intact GTF enzyme) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument that Shiroza et al do not teach or suggest a vaccine or immunogenic composition, but rather a mere protein sequence, it is noted that the protein of Shiroza et al has identical amino acid sequence to the claimed polypeptide and therefore the protein of Shiroza et al inherently has identical protein activity and identical immunogenicity to the claimed polypeptide.

6. The rejection of claims 1-11 and 15-17 under 35 U.S.C. 103(a) as being unpatentable over Shiroza et al (J Bacteriol 169: 4263-4270, 1987) and Taubman et al (US Patent 5,686,075) is maintained.

As discussed above, the protein of Shiroza et al has identical protein activity and identical immunogenicity to the claimed polypeptide. Therefore, the combination of Shiroza et al and Taubman et al <sup>makes obvious</sup> ~~will arrive to the level of~~ the claimed invention.

### ***Conclusion***

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7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Status of Claims*

8. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee  
December 7, 2000

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600